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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/506,361

02/18/2000

Marc Howard Spinoza

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/506,361	Applicant(s) SPINOZA, MARC HOWARD	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81-88,90-97,99 and 100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81-88,90-97,99 and 100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment filed on 5/29/09 has been entered.

Claims 81-88, 90-97, 99-100 are present for examination.

Claims 1-80, 89 and 98 are cancelled.

Specification

This disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01 (o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb. 2000)).

Appropriate correction is required.

Claim Objections

Claim 81 is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner has objected to the claims for the reason set forth above in the objection to the specification. Appropriate correction is required.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 81-88, 90-94, 95-97, 99-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sobin et al. (US 4,509,877) in view of Plass et al. (US 5,232,453).

Regarding claims 81-82, 84-88, 90-91, 94, Sobin discloses a fastener or strain relief device have also been used to protect the flexible member (catheter) to a rigid member comprising: a tubular sleeve 6 of variable length having a first aperture (at collar 7) through which a tube 1 can pass at a first end of the sleeve and a second aperture (at clamp 5) through which the tube can pass at the second end of the sleeve. It is inherently and well-known in the art that the medical device must be in sterile condition. Since the flexible member/catheter tube 1 is a medical device, it is well-known in the art that the catheter tube and the other parts (e.g. flexible tubular sleeve 6, collar 7, etc...) attached to the medical tube 1 must be in sterile condition also.

Sobin further discloses that the spacing between adjacent strands, at any given point, is a function of the distance between that point and the point of attachment of the flexible and rigid members. The apposition between the strands and the flexible member, or in other words the circumference of the braid itself, is constant, col. 3, lines 45-52. Beside that, when the sleeve 6 is fully extended, the sleeve 6 capable of gripping a tube to generate a compressive gripping force evenly distributed around the tube and along the length of the tube such that the sleeve with further length in response to movement of the tube of increase the compressive gripping force. Since the tubular sleeve 6 is flexible strands, therefore it is capable when lengthened of gripping a tube and when shortened of sliding along the tube 1; wherein the tubular sleeve has a perforated or foraminous wall that includes a plurality of filament helically woven to define a plurality of openings in the wall; the sleeve further comprises attachment means 7 or 3 or C. As noted that, the limitation "for attaching the sleeve to a patient" is a functional limitation, since the tube

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1 is catheter tube, therefore it is well-known in the art that the tube 1 can be attached to the patient. For example: if the attachment 3 or C comprises an adhesive layer at the bottom of element 3 or C or the element 7 can be hooked up with other attachment adhered to the patient.

Regarding claims 92-93, 95-97, 99-100, the sleeve 6 has a ring or collar 7, 8 at one end of the sleeve; the ring/collar surrounding the first and second apertures; and the collar holding together the free ends of the filaments making up the sleeve.

Plass discloses a catheter holder/attachment comprising: a tube 24, 26 (Figs. 1-5); an attachment 38A 12 or 32 attached into the patient.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "the tube can pass...long the tube" ; "the attachment of attaching the sleeve to a patient" of claims 1, 95; "a pad of flange for lying against part of the patient's body" of claim 85; "the pad or flange can be adhered or sutured to the patient's body" of claim 86, "an opening is capable of permitting the tube..." of claim 87; "the ring being operable to shorten or length of the sleeve" of claims 92, 95; functional limitations, do not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Sobin with an attachment device comprises adhesive, as taught by Plass, in order to adhere/attach the medical device with the patient for securing purpose.

Regarding claim 83, Sobin in view of Plass disclose the invention substantially as claimed. Sobin in view of Plass does not disclose that the loop is formed by doubling over the sleeve. However, it is common sense that one skill in the art would recognize that the loop formed of doubling for increasing strengthens.

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Claims 81-88, 90-94, 95-97, 99-100 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (US 3,122,806) in view of Bowen et al. (US 5,147,322) or Delk et al. (US 5,292,312).

Regarding claims 81-82, 84-88, 90-91, 94, Lewis discloses a gripping device have been used for pulling cables rope or other objects and may be used to pull lines over sheaves...(col. 1, lines 5+). As noted that, a catheter tube is analogous in structure to a cable line. One skill in the art to recognize that the cable line and the tube are interchangeable and can be used in medical arts as it relates with the tube. Therefore, the gripping device of Lewis can be applied for securing a tube to a patient. The device comprising: a tubular sleeve 2, since the device of Lewis is capable of applying for securing medical tubes, therefore it is well-known in the art that the device must be in sterile condition. The tubular sleeve 2 of variable length having a first aperture through which a tube/article 4 or 22 (Figs. 1-8) can pass at a first end of the sleeve and a second aperture through which a tube/article 4, 22 can pass at the second end of the sleeve, the sleeve capable when lengthened of gripping a tube (or the tubular body 2 is fully extended) to exert a compressive gripping force evenly distributed around the tube and along a length of the tube such that the sleeve with further lengthen in response to movement of the tube to increase the compressive gripping force (col. 3, line 70-col. 4, line 8); since the sleeve is woven and stretchable, therefore when shortened of sliding along the tube, wherein the tubular sleeve 2 has a perforated or foraminous wall that includes a plurality of filaments helically woven 7 to define a plurality of openings in the wall, and wherein the tubular sleeve 2 further comprise: attachments means 16 or 8 or 9 for attaching the sleeve to a patient, for example: the loop eyes can be made with the size that the hands inserted through the loop eyes 8.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "the tube can pass...long the tube"; "attachment for attaching the sleeve to a patient" of claims 81, 95; "a pad of flange for lying against part of the patient's body" of claim 85; "the pad or flange can be adhered or sutured to the patient's body" of claim 86, "an opening is capable of permitting the tube..." of claim 87; "the ring being operable to shorten or length of the sleeve" of claims 92, 95; functional limitations, do not impose any structural limitation upon the claimed apparatus

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which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Or Bowen discloses an attachment means 10 attaching the catheter tube to a patient, Figs. 1-2.

Delk discloses an attachment means 20, 30 attaching to the catheter tube to a patient, Figs. 1-2.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Lewis with an attachment, as taught by Bowen or Delk, in order to secured the medical device attached to a patient.

Regarding claim 83, Lewis in view of Bowen or Delk disclose the invention substantially as claimed. Lewis in view of Bowen or Delk does not disclose that the loop is formed by doubling over the sleeve. However, it is common sense that one skill in the art would recognize that the loop formed of doubling for increasing strengthens.

Regarding claims 92-93, 95-97, 99-100, Lewis discloses a ring/collar 16, 8 or 9.

Response to Arguments

Applicant's arguments with respect to claims 81-88, 90-97, 99-100 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763